1	UNITED STATES COURT OF APPEALS
2	FOR THE SECOND CIRCUIT
3	August Term, 2005
4	(Argued: November 14, 2005 Decided: August 22, 2006)
5	Docket No. 04-5337-cv
6	
7 8 9 10 11 12 13 14	Natural Resources Defense Council, Pesticide Action Network North America, The Breast Cancer Fund, Physicians for Social Responsibility, New York Public Interest Research Group, Farmworker Legal Services of New York, Citizens Campaign for the Environment, Neighborhood Network Research Center, Citizens Environmental Coalition, Mid-Hudson Catskill Rural and Migrant Ministry, Environmental Advocates of New York, Plaintiffs-Appellants,
16 17 18 19 20 21	v. Stephen L. Johnson, Administrator, United States Environmental Protection Agency,
22	<pre>Defendants-Appellees,</pre>
23 24 25 26 27 28 29	Captan Task Force, Makhteshim-Agan of North America, Inc., Sygenta Crop Protection Inc., Monsanto Company, Gowan Company L.L.C., Bayer CropScience LP, CropLife America, Defendants-Intervenors-Appellees.
31	B e f o r e: WINTER, STRAUB, and RAGGI, Circuit Judges.
32 33	Appeal from a dismissal of a complaint for lack of subject
34	matter jurisdiction, Fed. R. Civ. P. 12(b)(1), in the Southern
35	District of New York (Gerard E. Lynch, <u>Judge</u>). We affirm.

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WINTER, Circuit Judge:

The appellants in this action are eleven public health, environmental, religious and farmworker organizations, including the Natural Resources Defense Council (collectively, the "NRDC"

- 1 Appellants"). They appeal from Judge Lynch's dismissal of their
- 2 complaint for lack of subject matter jurisdiction.
- 3 The complaint challenged the Environmental Protection
- 4 Agency's ("EPA") decision to leave in effect certain pesticide
- 5 "tolerances" (i.e., the maximum permissible amount of pesticide
- 6 residues on food) for five pesticides after a systematic
- 7 tolerance reassessment program required by the Food Quality
- 8 Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
- 9 Judge Lynch dismissed the complaint after concluding that 21
- 10 U.S.C. § 346a(h)(5) required such challenges to be reviewed only
- in the courts of appeals after exhausting administrative review
- 12 processes. On appeal, the NRDC Appellants argue that Section
- 13 346a(h)(5) governs judicial review only of EPA decisions to
- 14 establish, modify, or revoke tolerances and that decisions to
- 15 leave tolerances in effect are reviewable in the district courts
- pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§
- 17 701 et seq.
- We affirm.
- 19 BACKGROUND
- 20 a) <u>Statutory and Regulatory Scheme</u>
- 21 The EPA regulates agricultural pesticides under two
- interrelated statutes: the Federal Food, Drug, and Cosmetic Act
- 23 ("FFDCA"), 21 U.S.C. §§ 301-394, and the Federal Insecticide,
- 24 Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y.

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          FIFRA imposes a federal licensing scheme on the sale,
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     distribution, and use of pesticides. 7 U.S.C. § 136a(a) ("no
     person in any State may distribute or sell to any person any
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     pesticide that is not registered" under FIFRA). A pesticide may
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     not be registered unless the EPA determines that "it will not
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     generally cause unreasonable adverse effects on the environment."
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     Id. § 136a(c)(5)(D). These environmental effects are analyzed,
     in part, by referencing the FFDCA and the "human dietary risk"
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     that might arise from pesticide residues in or on food. Id. §
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     136 (bb) (2).
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          To ensure the safety of consumers of pesticide-treated food,
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     the FFDCA empowers the EPA to establish "tolerances," which set
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     the maximum permissible level of pesticide residue on a
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     particular food, or to grant exemptions from the tolerance
     requirement. 21 U.S.C. §§ 346a(a)-(c). Before any agricultural
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     commodity containing pesticide residue can be sold or
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     distributed, a tolerance (or exemption) meeting certain safety
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     standards must be promulgated by the EPA. 21 U.S.C. §§ 331(a),
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     342(a)(2)(B), 346a(a)(1)-(2). If no tolerance or exemption is
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     established, any food containing pesticide residue is deemed
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     "unsafe" and "adulterated" and may not be moved in interstate
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     commerce.
                Id.
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          The EPA may "establish or leave in effect a tolerance for a
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pesticide chemical residue in or on a food only if the

- 1 Administrator determines that the tolerance is safe." Id. §
- 2 346a(b)(2)(A)(i). The term "safe" is defined to mean that "there
- 3 is a reasonable certainty that no harm will result from aggregate
- 4 exposure to the pesticide chemical residue, including all
- 5 anticipated dietary exposures and all other exposures for which
- 6 there is reliable information." Id. \$ 346a(b)(2)(A)(ii). Any
- 7 tolerance that is "not safe" must be modified or revoked. <u>Id.</u> §
- 8 346a(b)(2)(A)(i). If a pesticide is used on more than one food
- 9 crop, a separate tolerance (or exemption) must be established for
- 10 each pesticide-food combination.
- In 1996, both FIFRA and the FFDCA were amended by the Food
- 12 Quality Protection Act ("FQPA"), Pub. L. No. 104-170, 110 Stat.
- 13 1489. The FQPA required that the EPA reassess the safety of all
- then-existing tolerances -- over 9,000 -- and added to the FFDCA
- 15 a range of detailed, scientific factors to be considered in the
- assessment of pesticide risks. 21 U.S.C. \$ 346a(b)(2)(C)-(D).
- 17 Included in these factors were new requirements pertaining to the
- 18 safety of infants, children, and other major identifiable
- 19 subgroups. Id. § 346a(b)(2)(C) ("an additional tenfold margin of
- 20 safety . . . shall be applied for infants and children" unless
- 21 the EPA "on the basis of reliable data" establishes a "different
- 22 margin of safety" that "will be safe for infants and children");
- see also id. \$346a(b)(2)(D)(iv),(vi),(vii). Section
- 24 346a(q)(1) established a timetable for the reassessment of the

- 1 preexisting tolerances: 33% were to be completed by August 3,
- 2 1999, 66% were to be completed by August 3, 2002, and 100% were
- 3 to be completed by August 3, 2006. Id. \$ 346a(q)(1).
- 4 Under Section 346a(j)(3), a tolerance pre-dating FQPA's
- 5 enactment "shall remain in effect unless modified or revoked
- 6 under subsection (d) or (e) of this section [346a], and shall be
- 7 subject to review under" Section 346a(q). Id. 346a(j)(3). In
- 8 conducting its review of a particular tolerance under Section
- 9 346a(q), the EPA must determine whether it "meets the
- requirements of subsections [346a] (b) (2) or (c) (2)," and if it
- does not, "issue a regulation under subsection (d) (4) or (e) (1)
- of this section [346a] to modify or revoke the tolerance or
- 13 exemption." Id. \$ 346a(q)(1).
- 14 A reassessment review under Section 346a(q), therefore,
- 15 leads to one of two outcomes: if the EPA determines that the
- pre-existing tolerance meets the new safety standards of Section
- 17 346a(b)(2), the EPA leaves the tolerance in effect, and it is
- 18 considered reassessed under Section 346a(q); if the EPA finds the
- 19 pre-existing tolerance to be unsafe under Section 346a(b)(2),
- then it must modify or revoke the tolerance pursuant to Sections
- 346a(d)(4) or (e)(1). Id. § 346a(q)(1).
- 22 The establishment, revocation, or modification of a
- 23 tolerance occurs under the procedures set forth in Sections
- 346a(d)-(g). Id. \leq 346a(d)-(g). Section 346a(d) describes the

- 1 procedures by which the EPA may establish, modify or revoke a
- 2 tolerance in response to a petition from the general public. <u>Id.</u>
- 3 § 346a(d) ("Any person may file with the Administrator a petition
- 4 proposing the issuance of a regulation . . . establishing,
- 5 modifying, or revoking a tolerance for a pesticide chemical
- 6 residue in or on a food."). Upon receiving a petition, the EPA
- 7 must first determine whether the petition meets the requirements
- 8 governing petition contents. Id. § 346a(d)(2). If the
- 9 requirements are met, the EPA must publish a notice of the
- 10 petition's filing within thirty days. Id. § 346a(d)(3). After
- 11 publishing the notice, the EPA must issue a final regulation
- 12 establishing, modifying, or revoking the tolerance; issue a
- proposed regulation under the provisions of Section 346a(e) and
- 14 follow the procedures therein; or issue an order denying the
- 15 petition. Id. § 346a(d)(4)(A).
- Section 346a(e)(1) describes the procedures by which the EPA
- may, on its own initiative, "issue a regulation . . .
- 18 establishing, modifying, suspending . . . or revoking a
- 19 tolerance." Under Section 346a(e)(2), the EPA must issue a
- 20 notice of proposed rulemaking and generally provide at least
- 21 sixty days for public comment before issuing a final regulation.
- Once a regulation or order is issued pursuant to Sections
- 23 346a(d)(4) or 346a(e)(1), "any person" may file objections to the
- regulation or order within sixty days of its issuance,

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     "specifying with particularity the provisions of the regulation
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     or order deemed objectionable and stating reasonable grounds
     therefor." Id. § 346a(q)(2)(A). A public evidentiary hearing on
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     the objections may be held, id. § 346a(q)(2)(B), but "[a]s soon
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     as practicable after receiving the arguments of the parties, the
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     Administrator shall issue an order stating the action taken upon
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     each such objection and setting forth any revision to the
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     regulation or prior order that the Administrator has found to be
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     warranted." Id. § 346a(g)(2)(C).
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          The only provision relating to judicial review in Section
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     346a is subsection (h). Id. § 346a(h). Under Section
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     346a(h)(1),
                [i]n a case of actual controversy as to the
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               validity of any regulation issued under
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                subsection (e)(1)(C) of [§ 346a], or any
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                order issued under subsection (f)(1)(C) or
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                (g)(2)(C) of [\S 346a] . . any person who
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               will be adversely affected by such order or
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                regulation may obtain judicial review by
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                filing [in the United States Courts of
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               Appeals] . . . a petition praying that the
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                order or regulation be set aside in whole or
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                in part.
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Id. § 346a(h)(1). In sweeping language, Section 346a(h)(5) provides that "[a]ny issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law." Id. § 346a(h)(5).

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EPA's Implementation of the FQPA Amendments

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          Much of the tolerance reassessment program has been
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     conducted concurrently with a similar program under FIFRA to re-
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     evaluate pesticide registrations. See 7 U.S.C. § 136a-1.
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     EPA has frequently used "Reregistration Eligibility Decisions"
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      ("REDs") and "Interim Reregistration Eligibility Decisions"
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      ("IREDs") to announce its decisions on tolerance reassessment and
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     pesticide re-registration. See, e.g., 62 Fed. Reg. 42,020 (Aug.
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     4, 1997); 65 Fed. Reg. 37,375 (June 14, 2000).
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          REDs for two pesticides at issue in this case, alachlor and
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     captan, were issued in 1998 and 1999, respectively. U.S. EPA,
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     Reregistration Eligibility Decision (RED): Alachlor (1998)
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     (available at http://www.epa.gov/oppsrrd1/REDs/0063.pdf)
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      [hereinafter "Alachlor RED"]; U.S. EPA, Reregistration
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     Eligibility Decision (RED): Captan (1998) (available, as
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     amended, at http://www.epa.gov/oppsrrd1/REDs/0120red.pdf)
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     [hereinafter "Captan Red"]. Concluding "that the established
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     tolerances for alachlor, with amendments and changes as specified
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     in this document, meet the safety standards under the FOPA
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     amendments," the EPA determined that of 38 tolerances, five
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     should be revoked and six should be modified to contain an
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     increased tolerance value. Alachlor RED at 181, 185-87. Making
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     similar findings with respect to captan, the EPA found that 61 of
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     the 66 tolerances needed some sort of adjustment. Captan RED at
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62, 66-72.

- 1 The three other pesticides at issue in this case, diazinon, 2 disulfoton, and oxydemeton-methyl, are members of a large group of pesticides known as organophosphates, which share a common 3 4 mechanism of toxicity and whose exposure can cause cumulative 5 effects on humans. See 67 Fed. Reg. 56,557, 56,558 (Sept. 4, 6 2002). Because the EPA determined that the cumulative risks of 7 several organophosphates, including diazinon, disulfoton, and 8 oxydemeton-methyl, made at most minimal or negligible 9 contributions to the overall risk associated with 10 organophosphates, the tolerances for these organophosphates were 11 maintained "regardless of the outcome of the [organophosphate] 12 cumulative assessment and any potential regulatory action taken 13 as a result of that assessment." 67 Fed. Reg. 56,557, 56,558 14 (Sept. 4, 2002); see also 67 Fed. Reg. 56,555 (Sept. 4, 2002); 67 15 Fed. Reg. 52,987 (Aug. 14, 2002); 67 Fed. Reg. 46,972, 46,974 16 (July 17, 2002); 67 Fed. Reg. 35,991, 35,993 (May 22, 2002).
- 17 c) District Court Proceedings
- On September 15, 2003, the NRDC Appellants filed the present action.² On December 23, 2003, an amended complaint was filed challenging the EPA's reassessment and retention of tolerances for 146 pesticide-food pairs involving five pesticides: alachlor, captan, diazinon, disulfoton, and oxydemeton-methyl. Specifically, the NRDC Appellants argued that the EPA's decision to leave these tolerances in effect after reassessment was

- improper because: (i) the EPA ignored its statutory duty under the FFDCA to include an additional tenfold margin on safety in order to protect infants and children; (ii) the EPA failed to designate the children of farmworkers as a major identifiable subgroup especially vulnerable to the reassessed pesticides; (iii) for eleven organophosphates, the EPA left in effect tolerances whose level exceeded the safe level for children; (iv) for 120 tolerances, the EPA erroneously reduced the acute dietary risk posed by the pesticide by relying on data based on the estimated percentage of the crop treated with the pesticide; and (v) in violation of FIFRA, the EPA unlawfully relied on a confidential, proprietary computer model developed by the pesticide industry to conduct 118 organophosphate tolerance reassessments.
 - On March 25, 2004, the district court granted a motion to intervene on behalf of an association of pesticide manufacturers and distributors and several of its member companies (the "CropLife Appellees"). All appellees moved to dismiss the amended complaint on the ground that the district court lacked subject matter jurisdiction because the language of Section 346a(h)(5) specifically precluded district court review of the NRDC Appellants' challenges.

After holding that the disputed tolerance reassessments were final agency actions, the district court granted the motions to

- dismiss. It held that Section 346a(h) established an exclusive
- 2 procedure for obtaining judicial review and confined such review
- 3 to the courts of appeals. New York v. United States EPA, 350 F.
- 4 Supp. 2d 429, 437-46 (S.D.N.Y. 2004). Judicial review in the
- 5 district courts under the APA was therefore unavailable.
- 6 More specifically, the court found that the language of
- 7 Section 346a(h)(5):

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clearly demonstrates Congress's intent to preclude other avenues of review for determinations issued under the subsections to which it applies. Moreover, the provision's broad language, specifying that it covers "any issue as to which review is or was obtainable," indicates an intention to sweep in any challenge to an agency action that could have been appealed through the procedures it references, regardless of whether such internal review was actually pursued. That is, subsection [346a](h) explicitly applies not merely to cases in which administrative review was pursued, such that appellate review <u>is</u> obtainable under subsection [346a](h)(1), but also to cases in which such review was obtainable had the appropriate steps been taken. A litigant challenging an administrative decision governed by these provisions thus cannot, by skipping the internal review procedures of subsection [346a](q), avoid the jurisdiction of the Courts of Appeals and proceed instead to the District Courts under the APA, by arguing that, in the absence of an order under subsection [346a](q)(2)(C), subsection [346a](h)(1) is inapplicable.

36 Id. at 438. The district court concluded that the NRDC

37 Appellants could have challenged the EPA's reassessment decisions

using the procedures of Section 346a(d)(1) -- i.e., by filing a

- 1 petition to establish, modify, or revoke a tolerance -- setting
- 2 in motion a chain of events leading to judicial review under
- 3 Section 346a(h). Because "a determination to leave an existing
- 4 tolerance in effect would be reviewable in exactly the same
- 5 manner as any existing tolerance," "determinations made pursuant
- 6 to subsection (q) to leave tolerances in place should [not] be
- 7 treated any differently than decisions to modify or revoke them."
- 8 Id. at 441.
- 9 The district court also dismissed the NRDC Appellants'
- 10 claims of jurisdiction under FIFRA. <u>Id.</u> at 446-47. The district
- 11 court held that because Section 346a(h)(5) limited review "under
- 12 any other provision of law," "FIFRA's grant of jurisdiction is
- irrelevant." <u>Id.</u> at 446. Because the NRDC Appellants "challenge"
- 14 the registration of pesticides under FIFRA only through their
- challenge to the tolerances set under the FDCA," FIFRA did not
- represent an independent source of jurisdiction in this case.
- 17 Id. at 446.
- 18 DISCUSSION
- 19 a) Standard of Review
- "When reviewing a district court's Rule 12(b)(1)
- 21 determination of its subject matter jurisdiction, we review
- 22 factual findings for clear error and legal conclusions de novo."
- 23 Wake v. United States, 89 F.3d 53, 57 (2d Cir. 1996) (citation
- 24 and internal quotation marks omitted). Moreover "the court must

- 1 take all facts alleged in the complaint as true and draw all
- 2 reasonable inferences in favor of plaintiff." Sweet v. Sheahan,
- 3 235 F.3d 80, 83 (2d Cir. 2000).
- 4 b) Judicial Review under the APA
- 5 The APA provides that "[a] person suffering legal wrong
- 6 because of agency action, or adversely affected or aggrieved by
- 7 agency action within the meaning of a relevant statute, is
- 8 entitled to judicial review thereof." 5 U.S.C. § 702. This
- 9 provision permits review of "final agency action for which there
- is no other adequate remedy in a court." Id. § 704. However,
- 11 review under the APA may be excepted where: (i) "statutes
- 12 preclude judicial review; " or (ii) "agency action is committed to
- agency discretion by law." Id. § 701(a). These exceptions are
- 14 construed narrowly and apply only if there is "clear and
- 15 convincing evidence of legislative intention to preclude review."
- Japan Whaling Ass'n v. Am. Cetacean Soc'y, 478 U.S. 221, 230 n.4
- 17 (1986); see also Abbott Labs. v. Gardner, 387 U.S. 136, 141 & n.2
- 18 (1967), abrogated on other grounds by Califano v. Sanders, 430
- 19 U.S. 99 (1977).
- 20 "Whether and to what extent a particular statute precludes
- 21 judicial review is determined not only from its express language,
- 22 but also from the structure of the statutory scheme, its
- objectives, its legislative history, and the nature of the
- 24 administrative action involved." <u>Block v. Cmty. Nutrition Inst.</u>,

- 1 467 U.S. 340, 345 (1984); <u>see also Bowen v. Michigan Acad. of</u>
- 2 Family Physicians, 476 U.S. 667, 673 & n.4 (the presumption
- favoring judicial review may be overcome by "specific language"
- 4 or "inferences of intent drawn from the statutory scheme as a
- 5 whole"). Indeed, the "clear and convincing evidence" standard is
- 6 met, "and the presumption favoring judicial review overcome,
- 7 whenever the congressional intent to preclude judicial review is
- 8 fairly discernable in the statutory scheme." Block, 467 U.S. at
- 9 350-51 (citation and internal quotation marks omitted). However,
- 10 the clear and convincing evidence standard is "a useful reminder
- 11 to the courts that, where substantial doubt about the
- 12 congressional intent exists, the general presumption favoring
- judicial review of administrative action is controlling." <u>Id.</u> at
- 14 351.
- 15 Before addressing the NRDC Appellants' arguments that the
- 16 APA provides for judicial review in the district court, we must
- determine whether the challenged decisions represent final agency
- 18 action. If the decision to leave certain tolerances in place is
- 19 not final action, APA review would be inappropriate. See In re
- 20 <u>SEC ex rel. Glotzer</u>, 374 F.3d 184, 192 (2d Cir. 2004) ("Judicial
- 21 review under APA \S 702 is expressly conditioned, under APA \S 704,
- on the existence of a 'final' agency action.") (citing <u>Darby v.</u>
- 23 Cisneros, 509 U.S. 137, 146 (1993)). We agree with the district
- 24 court that the tolerance reassessments challenged were final

1 agency actions and adopt its reasoning.

c) Judicial Review Under the FFDCA

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- 3 Because the EPA's tolerance reassessments represent final 4 agency action, the APA permits review in the district court 5 unless it is "fairly discernable" that Section 346a precludes 6 judicial review. Block, 467 U.S. at 350-51. In analyzing 7 whether Section 346a precludes judicial review under the APA, we 8 first note that the FDCA is unique in that it only commits 9 certain specific agency actions to appellate court review. 10 Cutler v. Hayes, 818 F.2d 879, 888 n.61 (D.C. Cir. 1987). 11 Because the FDCA contains no "single, overarching provision 12 governing judicial review" -- instead subjecting "discrete agency 13 actions" to specialized review provisions -- actions taken under 14 sections silent as to appellate review are "directly reviewable 15 in a district court under some appropriate head of jurisdiction, 16 for courts of appeals have only such jurisdiction as Congress has 17 chosen to confer upon them." Id.; see also Alabama Tissue Ctr. 18 v. Sullivan, 975 F.2d 373, 376 (7th Cir. 1992); Nader v. EPA, 859 19 F.2d 747, 754 (9th Cir. 1988) (holding EPA's rejection of 20 rulemaking petition was not an order appealable to the court of 21 appeals because the sections permitting appellate review allowed 22 such review only of orders issued under subsections not 23 implicated in the litigation).
 - Despite the absence of an overarching judicial review

- 1 provision, both the language and the statutory scheme of Section
- 2 346a indicate that the district court lacked jurisdiction to
- 3 adjudicate actions such as those brought by the NRDC Appellants.
- 4 Section 346a(h)(5) states that "[a]ny issue as to which
- 5 review is or was obtainable under this subsection shall not be
- 6 the subject of judicial review under any other provision of law."
- 7 21 U.S.C. § 346a(h)(5). To determine whether the district court
- 8 has jurisdiction over the NRDC Appellants' claims, therefore, we
- 9 must determine whether their claims constitute "issue[s]" as to
- which review "is or was obtainable" under Section 346a(h). We
- 11 find that they do.
- 12 First, the language of Section 346a(h)(5) is quite
- expansive. Section 346a(h)(5) is not limited to certain defined
- actions or decisions; rather, its scope encompasses "[a]ny issue"
- 15 that could be addressed in the regulations and orders enumerated
- in Section 346a(h)(1). As such, an analysis of Section 346a(h)
- 17 requires us to look behind the specific agency action or decision
- 18 being challenged and to consider the issue being asserted by the
- 19 plaintiff.³
- Section 346a(h)(5)'s scope, however, incorporates only those
- 21 issues as to which review "is or was obtainable under this
- 22 <u>subsection</u> [346a(h)]." 21 U.S.C. § 346a(h)(5) (emphasis
- 23 supplied). Appellate review is limited, therefore, only to those
- 24 categories of issues to which review could have been obtained

- 1 under Section 346a(h)(1). By specifically referencing Section
- 2 346a(g)(2)(C), Section 346a(h)(1) permits review of those orders
- issued pursuant to Section 346a(g). Section 346a(g), in turn,
- 4 permits objections to orders issued pursuant to Section
- 5 346a(d)(4), which resolve petitions to establish, modify, or
- 6 revoke a tolerance under Section 346a(d)(1).5 Thus, if it is or
- 7 was possible to obtain review under the administrative review
- 8 procedures of Section 346a(q), then Section 346a(h) limits
- 9 judicial review to the courts of appeals and forecloses such
- 10 review prior to the exhaustion of administrative remedies. Cf.
- Nader, 859 F.2d at 753-54 (interpreting parallel pre-FQPA
- 12 provision of the FFDCA as requiring exhaustion of internal
- procedures before challenging denial of petition for rulemaking
- in court of appeals).
- 15 In mounting its challenge to those tolerance reassessments
- left in effect, the NRDC could have raised (and indeed still can
- 17 raise) every issue presented in their complaint in a petition to
- 18 modify or revoke the tolerance pursuant to Section 346a(d)(1)-
- 19 (2). 21 U.S.C. \S 346a(d)(1)-(2) ("any person" may petition for
- 20 an existing tolerance (or exemption) to be established, modified,
- or revoked) (emphasis supplied). The NRDC Appellants' request
- that the tolerances left in place be vacated and reassessed again
- is tantamount to a request for modification or revocation.
- 24 Applying the criteria espoused by the NRDC Appellants would de

- 1 facto result in a reduction or revocation of the tolerance for
- 2 each of the challenged pesticide-food pairs. That the NRDC
- 3 Appellants have not explicitly sought modifications or revocation
- 4 via Section 346a(d) does not alter the substance of their claims:
- 5 the EPA's failure to apply the correct standards during the
- 6 tolerance reassessments resulted in approval of heightened
- 7 pesticide residue levels.
- 8 Had the NRDC Appellants filed a Section 346a(d) petition
- 9 requesting modification or revocation of tolerances based on
- 10 those issues enumerated in their complaint, the EPA would have
- 11 been required to act by: (i) issuing a final regulation (which
- 12 could vary from that sought in the petition) modifying or
- revoking the tolerance; (ii) issuing a proposed regulation and
- 14 then final regulation pursuant to the procedures in Section
- 15 346a(e); or (iii) denying the petition. 21 U.S.C. § 346a(d)(4).
- 16 If the NRDC Appellants were dissatisfied with the EPA's
- disposition of their Section 346a(d) petition to modify or revoke
- 18 the tolerances, they could have objected to it under Section
- 19 346a(g)(2)(A). The EPA then would have been required to issue an
- order taking action on the objection. 21 U.S.C. \S 346a(g)(2)(C).
- 21 If the NRDC Appellants were dissatisfied with the EPA's Section
- 22 346a(g)(2)(C) order, Section 346a(h) clearly allowed them to
- obtain judicial review in the courts of appeal.
- 24 Hence, a challenge to a decision to leave a tolerance in

- 1 effect is an issue for which review was obtainable under Section
- 2 346a(h). As such, the NRDC Appellants are precluded from
- 3 obtaining "judicial review under any other provision of law." 21
- 4 U.S.C. § 346a(h)(5). Review in the district court under the APA,
- 5 therefore, is simply not proper for claims like those of the NRDC
- 6 Appellants. With respect to these types of claims, the text of
- 7 Section 346a(h) provides "clear and convincing evidence of
- 8 legislative intention to preclude review" under the APA. Japan
- 9 Whaling Ass'n, 478 U.S. at 230 n.4.

Furthermore, it is "fairly discernable" from the statutory scheme that jurisdiction is not appropriate in the district court. Block, 467 U.S. at 351. The NRDC Appellants' arguments, if adopted, would lead to a scheme in which the same tolerance would be subject to review by both the district courts and the courts of appeals at the same time: One party could directly challenge the EPA's decision to leave a tolerance in effect in a district court using APA review while, simultaneously, another party could trigger Section 346a(h) review in a court of appeals by following the administrative review process established in Section 346a(g) -- commencing with a Section 346a(d) petition to modify or revoke the same tolerance. It is highly unlikely that Congress intended to create a scheme involving multiple avenues of review and potential contradictory results. No evident policy goal would be served by such a scheme, and the statutory language

- 1 clearly suggests it was not intended.
- 2 The NRDC Appellants advance two main arguments in response.
- 3 First, they contend that a reassessment decision to leave a
- 4 tolerance in effect under Section 346a(q) is not one of the
- 5 enumerated types of agency action listed in Section 346a(h)(1),
- 6 see supra Note 3, and that Section 346a(h)(5) does not expand the
- 7 limited set of agency actions governed by Section 346a(h), see
- 8 21 U.S.C. § 346a(h)(5) ("Any issue as to which review is or was
- 9 obtainable under this subsection shall not be the subject of
- 10 judicial review under any other provision of law.") (emphasis
- 11 supplied). Second, the NRDC Appellants argue that Section
- 12 346a(q) is silent as to the review required for decisions to
- leave tolerances in effect. In contrast to Section 346a(q)'s
- 14 requirements for tolerances that do not meet the new strictures
- imposed by the FQPA, decisions to leave tolerances in place
- require no additional action by the EPA under Sections 346a(d) or
- 17 (g), eliminating the applicability of Section 346a(h)'s judicial
- 18 review provisions.
- 19 We conclude that these arguments are unavailing. While it
- is true that neither Section 346a(h)(1) nor (g) specifically
- 21 lists Section 346a(q) among the subsections to which it applies,
- 22 it does not follow that Section 346a(q) determinations to leave
- tolerances in place are necessarily excluded from its coverage.
- 24 The plain language of Section 346a(h)(1) and (5) is to the

- 1 contrary. As discussed above, the language of Section 346a(h)(5)
- 2 references "any issue" for which review "is or was obtainable
- 3 under this subsection." We find it implausible that a challenge
- 4 to the EPA's decision to leave certain tolerances in effect is
- 5 not an issue for which review is and was obtainable under Section
- 6 346a(g)(2)(C) -- which is specifically mentioned in Section
- 7 346a(h)(1) -- through Section 346a(d). While the NRDC Appellants
- 8 are challenging an EPA action not enumerated in Section
- 9 346a(h)(1), the fact remains that they are challenging an issue
- that does fall within the scope of Section 346a(h) because the
- 11 NRDC Appellants could have sought relief from the tolerance
- reassessments by petitioning to modify or revoke them under
- 13 Section 346a(d). The plain language of Section 346a(h) requires
- that this kind of challenge, along with any other issue for which
- review could be obtained under Section 346a(h), proceed under
- this subsection to the preclusion of "any other provision of
- 17 law." 21 U.S.C. § 346a(h)(5).
- Moreover, the NRDC Appellants' reliance on Sections
- 19 346a(g)'s "silence" as to judicial review is unavailing. Nothing
- in Section 346a(q) countermands Section 346a(h)(5)'s
- 21 applicability to decisions to leave tolerances in place. Indeed,
- 22 Section 346a(q) speaks solely to those actions required of the
- 23 EPA, not those of other parties. Under Section 346a(q), if the
- 24 EPA determines that a tolerance should be left in effect, there

- 1 is nothing more for the EPA to do. Any additional steps
- 2 necessary for objecting parties to challenge decisions to leave
- 3 tolerances in effect is not the subject of Section 346a(q).
- 4 Instead, Section 346a(h) governs these kinds of challenges, which
- 5 must be brought in the first instance pursuant to the procedures
- 6 in Sections 346a(d) and (q).
- 7 Furthermore, those cases cited by the NRDC Appellants as
- 8 supporting district court jurisdiction are quite distinguishable
- 9 from the present case. In NRDC v. Whitman, No. 99-03701, 2001 WL
- 10 1221774 (N.D. Cal. Sept. 24, 2001), the NRDC sued the EPA in
- 11 district court for failing to meet the statutory deadlines for
- 12 tolerance reassessment under Section 346a(q). The district court
- found that it had jurisdiction over the plaintiffs' claims
- because Section 346a(q)(3) specifically states that "'failure to
- 15 take final action pursuant to the schedule established by this
- paragraph shall be subject to judicial review." Id. at *10
- 17 (quoting 21 U.S.C. \S 346a(q)(3)) (emphasis in original). The
- 18 district court, therefore, had jurisdiction over these claims
- 19 based on specific language in Section 346a(q)(3), not because all
- 20 actions and decisions under Section 346a(q) are somehow outside
- 21 the scope of Section 346a(h)'s judicial review scheme.
- The NRDC Appellants also rely on American Farm Bureau v.
- 23 EPA, 121 F. Supp. 2d 84 (D.D.C. 2000). In American Farm Bureau,
- 24 the plaintiffs challenged, <u>inter alia</u>: (i) the EPA's failure to

1 promulgate regulations governing tolerances for emergency exemptions pursuant to Section 346a(1)(6); (ii) the EPA's failure 2 3 to promulgate data requirements for tolerances pursuant to 4 Section 346a(d)(2)(A); (iii) the EPA's imposition of a 99.9th percentile policy that created a "legislative rule" in violation 5 6 of the APA's notice and comment requirements; and (iv) the EPA's 7 imposition of a child and infant safety factor policy that also formulated a "legislative rule" in violation of APA notice and 8 9 comment requirements. Id. at 89-90, 93. The EPA argued that 10 each of these challenges sought to compel the issuance of "general procedures" under Section 346a(e)(1)(C) and, as such, 11 12 were only reviewable in the courts of appeals under Section 13 346a(h). The district court disagreed and found that it could 14 exercise jurisdiction over the plaintiffs' claims. Id. at 91, 15 92-93. Because Section 346a(e)(1)(C) governed discretionary 16 action only and the plaintiffs' claims were based entirely on 17 statutorily mandated actions, none of the claims fell within the 18 scope of appellate review contemplated by Section 346a(h). Id. 19 at 93-94.

The present case is distinguishable from American Farm

Bureau because the plaintiffs there were challenging the EPA's general policy decisions and failure to issue regulations. These issues could not have been raised using Sections 346a(d) or (g), as these subsections are limited to petitions for establishing,

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- 1 modifying, or revoking specific tolerances, not the general
- 2 policies and standards under which the tolerances are assessed in
- 3 the first place. On the other hand, the NRDC Appellants here are
- 4 challenging specific tolerance reassessments -- the failure to
- 5 apply the correct policy and standards to particular pesticide-
- 6 food pairs. These claims could have been addressed using the
- 7 procedures in Sections 346a(d) and (g), and thus (h).
- 8 Because the NRDC Appellants' claims involve issues that
- 9 could have been raised using the procedures enumerated in Section
- 10 346a(h), this section controls and judicial review is limited to
- 11 the courts of appeals.
- d) Judicial Review Under FIFRA
- Even if the FFDCA precludes review of their claims under the
- 14 APA, the NRDC Appellants claim that FIFRA Section 16a, 7 U.S.C. §
- 15 136n(a), provides an alternative ground for jurisdiction.
- 16 Section 16a states:
- 17 Except as otherwise provided in this 18 subchapter, the refusal of the Administrator 19 to cancel or suspend a registration or to 20 change a classification not following a 21 hearing and other final actions of the 22 Administrator not committed to the discretion 23 of the Administrator by law are judicially 24 reviewable by the district courts of the 25 United States.
- 26
- 7 U.S.C. § 136n(a). The NRDC Appellants attempt to avail
- themselves of Section 16a by claiming that the EPA used a
- 29 confidential computer model to conduct pesticide exposure

1 assessments even though under FIFRA such a model must "be 2 available for disclosure to the public." 7 U.S.C. § 136h(d)(1). However, FIFRA's grant of jurisdiction to the district 3 4 courts is irrelevant. The NRDC Appellants "challenge the 5 registration of pesticides under FIFRA only through their 6 challenge to the tolerances set under the FDCA." New York v. 7 United States EPA, 350 F. Supp. 2d at 446. Essentially, 8 therefore, the violations of FIFRA alleged by the NRDC Appellants 9 "amount to challenges to the methodologies used in reaching the reassessment determinations at issue" in this case. <u>Id.</u> As 10 11 such, these challenges represent an "issue as to which review is 12 or was obtainable" under Section 346a(h). 21 U.S.C. § 13 346a(h)(5). Section 346a(h)(5) precludes judicial review of

these issues "under any other provision of law." The NRDC

the statutory provisions for administrative review.

Appellants' attempt to find independent jurisdiction for their

claims under FIFRA is thus precluded by the express language of

Section 346a(h)(5). The NRDC Appellants' claims are reviewable

only in the courts of appeals, and only after they have exhausted

20 CONCLUSION

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For the foregoing reasons, the district court properly dismissed the complaint for lack of subject matter jurisdiction. The decision of the district court is therefore affirmed.

1 FOOTNOTES

- 1. EPA Administrator Stephen L. Johnson is substituted as Defendant-Appellee. See Fed. R. App. P. 43(c)(2).
 - 2. An action filed by the states of New York, New Jersey,
 Connecticut, and Massachusetts was consolidated with the NRDC
 Appellants' action because both lawsuits challenged the safety of
 certain EPA pesticide reassessment decisions, and thus involved
 common questions of fact and law. Although the district court's
 order and opinion dismissed both lawsuits, the state plaintiffs
 have not appealed.
 - 3. An issue is defined as "[a] point in dispute between two or more parties" and is not limited to particular kinds of actions. Black's Law Dictionary 835 (7th ed. 1999); see also Webster's Third New Int'l Dictionary 1201 (1981) ("a matter that is in dispute"; "a point in question in law or fact").
 - 4. Section 346a(h)(1) also permits review of regulations issued under Section 346a(e)(1)(C) and orders issued under 346a(f)(1)(C). These regulations and orders are not at issue in this case; therefore, our analysis is limited to those orders issued pursuant to Section 346a(g)(2)(C).

5. Section 346a(g)(2)(A) permits "any person" to object to a regulation or order "issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C)..." For purposes of this case, however, we are only concerned with Section 346a(g)(2)(C) orders issued in response to an objection to an order issued under Section 346a(d)(4).